DOCKET NO.: PUAM-0257 **Application No.:** 10/631,883

Office Action Dated: DECEMBER 31, 2007

REMARKS

Claims 1, 5, 6, 26, 27, 102, 103, 105-107 and 116 are currently pending.

Applicants wish to thank the examiner for the courtesy of an interview on April 2, 2008. Examiner Lundgren and the undersigned counsel discussed certain functional groups on the core glycopeptide structure of the claims and possible claim amendments.

The present invention is directed to modified vancomycin glycopeptide antibiotics. The structure of naturally occurring vancomycin is show below.

Vancomycin contains a disaccharide moiety covalently linked to a heptapeptide (i.e., sevenmer peptide) structure. The heptapeptide is represented by residues A₁ through A₇ shown above. Attached to residue A₄ is a glucose residue, which in turn is linked to another sugar

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residue. The present invention includes a modified vancomycin, wherein the heptapeptide structure of naturally occurring vancomycin is maintained, and the sugar residues linked through the A₄ residues are substituted with various substitutions. One such substitution occurs at the C-6 position of the glucose residue attached directly to the A₄ residue. Another substitution occurs at the vacomycin nitrogen of the second sugar residue.

Claim rejections under 35 U.S.C. §112, first paragraph (scope of enablement)

Claims 1, 5, 6, 26, 27, 102, 103, 105-107, and 116 stand rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement. Applicants traverse this rejection because the claims as written are enabled, and one skilled in the art would be able to make and use the invention.

Independent claims 1 and 102 clearly define Applicants' invention. Claim 1 recites a "glycopeptide of the formula A₁-A₂-A₃-A₄-A₅-A₆-A₇, [SEQ ID NO:1] wherein the groups A₁ to A₇ comprise the heptapeptide structure of naturally occurring vancomycin...wherein the group A₄ is linked via a glycosidic bond to a disaccharide having a glucose residue directly attached to said A₄ residue, wherein said glucose residue bears an N-substituted aminohexose residue selected from the group consisting of allyloxycarbonyl, N-decyl, and N-4-(4-chlorophenyl)benzyl and a substituent of the formula YXR, attached to the C-6 position of said glucose," thereby providing clarity to the claimed C6 and N-substituted aminohexose modified vancomycin glycopeptides. Likewise, claim 102 recites a vancomycin glycopeptide antibiotic with glucose C6 modifications.

Support for the claims can be found throughout the specification, including, for example at page 21, lines 25-27; page 15, lines 31; and various examples, including examples 19, 20, 53-55, 59-67. The scope of the claims is thus adequately supported by the specification.

It is noted that the Examiner admits that the specification "shows support for the heptapeptide structure of naturally occurring vancomycin." Action at 3. Applicants submit that the claims currently presented are not beyond the scope of that taught by the specification. Therefore, Applicants submit that the pending claims are sufficiently enabled and request withdrawal of the rejection.

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Claim rejections under 35 U.S.C. §112, first paragraph (written description)

Claims 1, 5, 6, 26, 27, 102, 103, 105-107, and 116 stand rejected under 35 U.S.C. §112, first paragraph for alleged lack of written description. Applicants traverse this rejection because the claims as written reasonably convey to one of skill in the art that Applicants were in possession of the invention at the time of filing. Claim 1 recites a "glycopeptide of the formula A₁-A₂-A₃-A₄-A₅-A₆-A₇, [SEQ ID NO:1] wherein the groups A₁ to A7 comprise the heptapeptide structure of naturally occurring vancomycin...wherein the group A₄ is linked via a glycosidic bond to a disaccharide having a glucose residue directly attached to said A₄ residue, wherein said glucose residue bears an N-substituted aminohexose residue selected from the group consisting of allyloxycarbonyl, N-decyl, and N-4-(4chlorophenyl)benzyl and a substituent of the formula YXR, attached to the C-6 position of said glucose," thereby providing clarity to the claimed C6 and N-substituted aminohexose modified vancomycin glycopeptides. Likewise, claim 102 recites a vancomycin glycopeptide antibiotic with glucose C6 modifications. These claims clarify that the invention encompasses modified vancomycin glycopeptides, which is adequately described throughout the specification, including as evident by the Table of synthesized compounds appearing at pages 131-135, and otherwise throughout the specification including, for example at page 21, lines 25-27; page 15, lines 31; and various examples, including examples 19, 20, 53-55, 59-67.

At the time the application was filed, as evidenced by the specification, applicants were in possession of a modified vancomycin glycopeptide wherein the modifications included both a substituted glucose residue (attached directly to residue A_4 of the vancomycin heptapeptide core) at the C-6 position of the glucose, and an N-substituted aminohexose residue wherein the substitution is selected from the group consisting of allyloxycarbonyl, N-decyl, and N-4-(4-chlorophenyl)benzyl. Applicants submit that it would be apparent to one of ordinary skill in the art that Applicants were in possession of the claimed invention at the time of filing, thereby fulfilling the requirements of the first paragraph of 35 U.S.C. §112. Withdrawal of the written description rejections is requested.

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Rejection Under 35 U.S.C. §102(a)

Claims 1, 5, 6, 26, 27, 102, 103, 105-107, and 116 stand rejected under 35 U.S.C. §

102(a) as allegedly anticipated by Ge et al., J. Am. Chem. Soc. 120:11014-11015 (1998)

("the Ge reference"). Applicants traverse this rejection.

According to page 11014 of the Ge reference, the Ge reference was published on the

web on October 10, 1998, and hence available as a §102(a) reference as its publication date.

The present invention claims priority to U.S. Patent Application No. 09/353,368, filed July

14, 1999, which in turn claims benefit of Provisional Application Serial No. 60/134,839 filed

May 19, 1999, as well as benefit of U.S. Patent Application No. 09/115,667, filed July 14,

1998 (since converted to Provisional Application No, 60/150,690). Since Applicants have

perfected a priority claim to July 14, 1998, which pre-dates Ge's publication date, Applicants

submit that Ge is not a proper §102(a) reference and request that the rejection over Ge be

withdrawn.

Conclusion

Applicants submit that claims 1, 5, 6, 26, 27, 102, 103, 105-107, and 116 are in

condition for allowance. An early Notice of Allowance is respectfully requested. If the

Examiner disagrees, he is invited to telephone the undersigned.

Date: April 30, 2008

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